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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/444,388	11/22/99	HIBINO T	P21-9042

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EXAMINER	
SOUAYA,J	
ART UNIT	PAPER NUMBER
1655	6

DATE MAILED: 03/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

.Office Action Summary	Application No. 09/444,388	Applicant(s) Hibino et al
	Examiner Jehanne Souaya	Group Art Unit 1655

☒ Responsive to communication(s) filed on *Nov 22, 1999*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-7* is/are pending in the application.

Of the above, claim(s) *6 and 7* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-5* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *2*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, drawn to a method for obtaining a plant DNA fragment and to a gene encoding the fragment, classified in class 435, subclass 6; and class 536, subclass 23.1 respectively.

II. Claims 6-7, drawn to a transgenic plant a method of breeding the plant, classified in class 800, subclass 267.

2. The inventions are distinct, each from the other because of the following reasons: The inventions of groups I and II are drawn to different products having different structures and functions. The nucleic acid of group I is composed of deoxyribonucleotides linked by phosphodiester bonds and assumes the form of a double helix. The transgenic plant of group II is composed of highly ordered cells that in term make up tissue, that then in turn make up systems and ultimately the plant organism. The methods required to produce the nucleic acid of group I requires different reagents, reaction parameters, and reaction conditions than the method required to produce the transgenic plant of group II. While the transgenic plant of group II is made of DNA, the nucleic acids of group I can be used in a materially different assay than the transformation of the plant in group II, such as in hybridization assays. Consequently, the

reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of groups I and II are patentably distinct from each other.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

5. During a telephone conversation with Douglas Goldhush on January 18, 2001 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-5. Affirmation of this election must be made by applicant in replying to this Office action. Claims 6-7 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Priority

7. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

8. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 2-4 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. For example, Claim 3 is directed to a gene which is non-statutory subject matter. Applicants can overcome this rejection by reciting instead --an isolated gene...--. Claim 2 should recite "any --isolated-- DNA fragment..."; and claim 4 should recite " --An isolated-- DNA (--or nucleic acid sequence--) with promoter activity..."

Claim Rejections - 35 USC § 112

Written Description

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a process for obtaining any plant DNA fragment by digesting DNA from any plant, subjecting the fragments to subtractive hybridization to obtain polymorphic fragments and screening the fragments to obtain a desired fragment. The claims are further drawn to any fragment obtained by this method, including any gene and any DNA with promoter activity. The specification teaches a general method of digesting plant DNA to form DNA fragments, subjecting the DNA fragments to genome subtraction to obtain polymorphic fragments, and screening the polymorphic DNA fragments for a desired DNA fragment (see p 3). More specifically, the specification teaches that the RDA method was used as the genome subtraction method (see p. 8, line 31). The specification teaches that two siblings, *Acacia auricaliformis,* were seeded at the same time and allowed to grow. After 2 years, a difference in 50 cm was found in tree height and a 2 cm difference was found in root diameter (see sentence bridging pp 8 and 9). The specification teaches using genomic DNA prepared from each leaf in a

method of genome subtraction where total RNA was extracted (p. 9, line 5), and a DNA fragment obtained after subtraction was fractionated by acrylamide gel electrophoresis (p. 9, lines 29-32). The specification teaches that positive DNA fragments were sublconed and analyzed. The specification teaches that 6 DNA fragments were obtained (see p. 10, lines 20-22, and FIG 1). The specification teaches that FIG 1 shows the results of genome subtraction and hybridization by an expression probe for acacia, and that the circles indicate DNA fragments selected by subtraction that were judged to be complementary with the experimental probe (see p. 11, lines 1-2). The specification, however, does not teach a) such a process for obtaining *any* DNA fragment from a plant, b) the nucleic acid sequence of this DNA fragment, c) the gene sequence of such a fragment, d) a DNA sequence with promoter activity, or e) an expression vector comprising this fragment. Each of the claimed inventions is a genus for which a representative number of species must be disclosed to meet the written description requirement of 112/1st paragraph. As set forth by the Court in *Vas Cath In. V. Mahurkar,* 19, USPQ2d 1111, the written description must convey to one of skill in the art "with reasonable clarity" that as of the filing date applicant was in possession of the claimed invention. The specification only teaches a general method of obtaining DNA fragments from plants using genome subtraction. The specification teaches obtaining fragments from *Acacia auricaliformis*, but does not teach if these fragments were in any way related to the difference in height and root diameter observed between the two plants. Furthermore, the specification only shows gel with bands corresponding to DNA fragments, but does not teach the sequence of such DNA fragments. The specification also fails to teach a gene,

or a DNA with promoter activity, or a vector sequence comprising such fragments. The claims are drawn to specific products which encompass nucleic acid sequences, however the specification does not teach a single example of such. The specification has only taught a broad method, and the successful isolation of DNA fragments, but has not taught whether these fragments were the "desired" fragments as encompassed by the claimed invention. Absent such a written description, the specification fails to show that applicant was in fact "in possession of the claimed invention at the time the application for patent was filed.

Indefinite

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in the recitation of "RNA derived probe" as it is unclear whether the term refers to a probe that hybridizes to cDNA or to a probe that has been altered in some way. It is unclear from the recitation what the probe is derived from.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claim 1 is rejected under 35 U.S.C. 102(b) as anticipated by Wigler et al (US Patent 5,436,142) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wigler et al (US Patent 5,436,142).

Wigler teaches method for representational different analysis (RDA) between two sources of DNA (see col. 2, lines 28-30). Wigler teaches that the method involves the isolation of DNA, where the DNA can be from any source, including plants (see col. 3, lines 47-51). Wigler teaches that in the first stage, DNA is isolated and digested to produce fragments (col. 3, lines 61-65). Wigler teaches that subtractive and kinetic steps are employed in the next stage, in a single

operation of hybridization and amplification, which, after several rounds, produces enrichment of target DNA (col. 4, lines 29-65). Wigler teaches that resulting DNA can be used as probes to identify sites which differ (col.5). Wigler teaches that such analysis can be used to define sequences which are present in one member of a family and not in another (see col. 6, lines 1-15). In example 2, Wigler specifically teaches analysis of DNA from two individuals resulting in the detection of a small number of differences between two nearly identical genomes. Although Wigler does not directly teach such a method in obtaining plant DNA fragments, Wigler does teach that such a method can be used for analysis of plants.

18. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Phillips et al (Plant Molecular Biology, vol. 24, pp 603-615, 1994).

Phillips teaches a subfraction cloning scheme for Arabidopsis thaliana, which resulted in the isolation of differentially regulated cDNA (see abstract). The method of Phillips involves isolating total mRNA from plant material (p. 604), followed by subtractive hybridization using excess 'driver' poly(A)+ RNA form control treated plants with first strand cDNA from GA treated plants to generate polls of either GA induced or Ga repressed sequences (see p. 605, co. 1). Phillips teaches that clones representing mRNA changed in abundance by GA were selected from enriched libraries by differential hybridization (see p. 607, col. 1 "Identification of GA-regulated clones). Phillips teaches that the probes for differential hybridization were generated form single strands cDNA (p. 607, co. 1). Phillips teaches that the technique was used to identify

two genes whose corresponding mRNA accumulate 24 h after application of GA3 to plants of the Arabidopsis thaliana GA-deficient dwarf mutant ga1 (p. 613, col. 1, "Discussion").

Conclusion

19. No claims are allowable.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Thursday from 7:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya
Jehanne Souaya
Patent examiner
March 29, 2001

W. Gary Jones
Supervisory Patent Examiner
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3/26/01